

REMARKS

Applicants submit this paper in response to the final office action the Office mailed on May 18, 2007.

Independent claims 119 and 139 are amended to recite the dosing regimens that dependent claims 120 and 142 recited. The amendments introduce no new matter.

Commonly Owned Applications

The Office's attention is directed to commonly owned copending U.S. patent application serial Nos. 11/835,334, 11/835,367, 11/835,394 and 11/835,397, all filed August 7, 2007. The subject matter claimed in this application and in these newly filed applications does not overlap.

35 USC 102(b)

In the final office action the Office mailed on May 18, 2007, claims 119, 130, 139 and 141 under Section 102(b) as anticipated in view of U.S. patent 5,461,042 or U.S. patent 5,387,583. Amended independent claims 119 and 139 and dependent claims 130 and 141 now recite dose regimens that neither patent discloses and the rejection should be withdrawn.

Applicants request reconsideration and withdrawal of the rejection.

35 USC 103(a)

In the final office action the Office rejected claims 119-146 allegedly as obvious in view of U.S. patent 5,461,042 or D.J.J. Carr, *J. Neuroimmunol.*, 89:160-167, 1998. Applicants maintain their traverse of the rejection for reasons of record. In particular, Applicants maintain their assertion that this rejection is based on hindsight, which is improper. *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. ____ (2007); *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999). Because of this, Applicants respectfully submit that the Office has not established a *prima facie* case of obviousness and the rejection should be withdrawn.

In addition, Applicants provided evidence of unexpected efficacy in non-human primates as discussed in the declaration submitted on February 21, 2007 and in Applicant's prior response. Efficacy was observed in humans in the face of factors

mitigating for non-efficacy (see, e.g., J.E. Layton et al., *Blood*, 74(4):1303-1307, 1989, of record) Carr, (cited above) showed that 32 mg/kg and 100 mg/kg 3 β ,17 β -dihydroxyandrost-5-ene dosages were inactive in Carr's clinical setting (HSV-1 infection). Collectively, these are all evidence of non-obviousness. *Graham v. John*

5 *Deere Co.*, 383 U.S. 1 (1966).

In view of the record, Applicants respectfully request reconsideration and withdrawal of the rejection.

Respectfully submitted,

10 Date: August 8, 2007

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